

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm - SEMESTER-I • EXAMINATION – WINTER-2016

Subject Code:910104**Date: 02/01/2017****Subject Name: Biological Evaluations and Clinical Research****Time: 10.30 AM – 01.30 PM****Total Marks: 80****Instructions:**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

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| Q.1 | (a) | What is sterility testing? Describe membrane filtration method for the assessment of sterility of liquids. | 06 |
| | (b) | Enlist Depyrogenation techniques. Discuss ANY TWO in detail. | 05 |
| | (c) | Write a note on LAL test for detection of pyrogens. | 05 |
| Q.2 | (a) | What is bioassay? Describe the methods for evaluation of Bioassay. | 06 |
| | (b) | Discuss the objective and importance of Bioassay. Explain bioassay of Oxytocin. | 05 |
| | (c) | What is Radioimmunoassay? Discuss Radioimmunoassay of Insulin. | 05 |
| Q.3 | (a) | What are clinical trials? Discuss different phases of Clinical trials. | 06 |
| | (b) | Explain the role of Institutional Review Board and Investigator in Good Clinical Practice guidelines. | 05 |
| | (c) | Write a note on Helsinki Declaration. | 05 |
| Q.4 | (a) | Write a note on Extraction of drugs from biological matrix. | 06 |
| | (b) | What are biological samples? Give types and collection methods for biological samples. | 05 |
| | (c) | Describe chemistry of pyrogens and endotoxins. Explain mechanism of action of pyrogens. | 05 |
| Q.5 | (a) | Define: Bioavailability and Bioequivalence. Explain Urinary excretion method used for measurement of bioavailability. | 06 |
| | (b) | Discuss in vitro methods for the assessment of bioavailability. | 05 |
| | (c) | Discuss different Bioequivalence study design and protocol in detail. | 05 |
| Q. 6 | (a) | Explain the terms C_{max} , t_{max} , AUC and V_d . Discuss the Importance of Pharmacokinetic study. | 06 |
| | (b) | What are Pharmacokinetic models? Discuss advantages of compartment models and Explain Mammillary model in detail. | 05 |
| | (c) | Write a note on Study of Teratogenicity and Mutagenicity. | 05 |
| Q.7 | (a) | Explain Chronic and sub acute toxicity studies in detail. | 06 |
| | (b) | What is the significance of microbial limit test? Describe methods for testing effectiveness of preservatives. | 05 |
| | (c) | Describe One compartment open model i.v. bolus administration. | 05 |
